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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,400	10/22/2001	Neal D. Epstein	4239-61090	5338

7590 07/28/2003

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EXAMINER

LI, QIAN J

ART UNIT	PAPER NUMBER
1632	7

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/003,400	EPSTEIN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Q. Janice Li	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 03 June 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-12,25 and 43-50 is/are pending in the application.

4a) Of the above claim(s) 44-48 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-12,25,43,49 and 50 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-12, 25, 43, 49, and 50, in Paper No. 6 is acknowledged. The traversal is on the ground(s) that that a search of claims of Groups VI and I can be made without serious burden. This is not found persuasive because it is maintained that each of the Inventions requires a separate search status and consideration. The product of group I could be used in preparing a pharmaceutical composition for treating a subject as claimed in group IV, and the screening process could be practiced with a materially different product such as a cardiomyocyte precursor cells of marrow stromal cells. As such, the Invention of group VI requires different search criteria and distinct technical considerations. The searches for groups VI and I would have certain overlap, but they are not co-extensive. M.P.E.P. states, "FOR PURPOSES OF THE INITIAL REQUIREMENT, A SERIOUS BURDEN ON THE EXAMINER MAY BE PRIMA FACIE SHOWN IF THE EXAMINER SHOWS BY APPROPRIATE EXPLANATION OF SEPARATE CLASSIFICATION, OR SEPARATE STATUS IN THE ART, OR A DIFFERENT FIELD OF SEARCH AS DEFINED IN MPEP § 808.02". Therefore, it is maintained that these inventions are distinct due to their divergent subject matter. Further search of these inventions is not co-extensive, as indicated by the separate classifications. The requirement is still deemed proper and is therefore made **FINAL**.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the

Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Claims 1-12, 25, and 43-50 are pending, however, claims 44-48 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim.

Claims 1-12, 25, 43, 49, and 50 are under current examination.

### ***Claim Objections***

Claim 25 is objected to because it depends from a canceled claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 25, 43, 49, and 50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for obtaining an isolated mammalian c-kit-/c-met- cardiomyocyte precursor cell from *skeletal* muscle cells having the size of 3-10 mm and c-kit-/c-met-, does not reasonably provide enablement for obtaining an isolated mammalian c-kit-/c-met- cardiomyocyte precursor cell from *any* cell of muscular origin or any size of the skeletal muscle cells. The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the scope of the claims relative to the state of the art, and whether sufficient amount of direction or guidance are provided in the specification to enable one of skill in the art to practice the claimed invention.

Given the broadest reasonable interpretation, the cardiomyocyte precursor cells could be derived from any cell of muscular origin, such as smooth muscle cells and cardiac muscle cells. However, the specification teaches in example 7 that only the skeletal muscle spoc cell, not the cells obtained from heart could differentiate into the beating cardiomyocytes, thus, the claims do not appear to be enabled to its scope in light of the teachings of the specification. Further, the specification is silent with respect to the smooth muscle cells, considering the negative data obtained from cells derived from heart, it could not be predictably determined that smooth muscle cells containing the precursors of cardiomyocyte. It would have required undue experimentation for the

skilled artisan intending to practice the instant invention commensurate with the scope of the claims.

Given the broadest reasonable interpretation, the cardiomyocyte precursor cells could be obtained from skeletal muscle cells of any size. However, the specification teaches first sorting the skeletal muscle cells according to its size (ranging from 4-10  $\mu\text{m}$ ), followed by sorting the cells according to the surface markers (c-kit-/c-met-), and the resulting cell population is capable of differentiating into the beating cardiomyocytes. The specification is silent with respect to the differentiation capability of the population of skeletal muscle cells that are c-kit and c-met negative but having larger sizes. Considering that the c-kit and c-met are stem and precursor cell markers, it is highly possible that a larger sized and c-kit-/c-met- skeletal muscle cell population does exist, and does not have the capability of transdifferentiating into the beating cardiomyocytes. Thus, the claims do not appear to be enabled to its scope in light of the teachings of the specification.

Claim 49 is directed to a kit for promoting cardiomyocyte differentiation comprising a purified population of mammalian c-kit-/c-met- cardiomyocyte precursor cells of muscular origin, however, the specification fails to teach how such cells by themselves could promote the differentiation of a cardiomyocyte, thus, fails to provide sufficient guidance for practicing the invention.

It is noted that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991).

Therefore, in view of the limited guidance, the lack of predictability of the art and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation as it is broadly claimed.

***Conclusion***

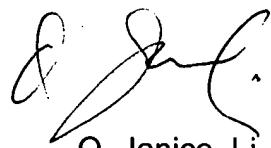
No claim is allowed. Claims 1-12, 25, 43, 49, and 50 appear to be free of prior art of record, however, they are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).



Q. Janice Li  
Examiner  
Art Unit 1632

QJL  
July 25, 2003